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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/523,096

08/31/2005

Robert A Levine

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

01/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/523,096

Applicant(s)

LEVINE ET AL.

Examiner

Henry M. Johnson, III

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 56-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 56-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Arguments***

Applicant's arguments with respect to claims filed on August 9, 2007 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the acute angle is define relative to the surface as the wire is essentially circular and presents multiple angles.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,643,248 to Yoon. Yoon discloses a medical instrument including a probe with a hook at a distal end. The probe may be any type of implement having a configuration useful for medical purposes including, for example, cutting members such as blades, penetrating members such as needles, cannulae such as portal sleeves, safety shields and catheters, cauteries, grasping implements such as hooks and forceps, biopsy tools and viewing probes

such as endoscopes. The device includes a hollow cylindrical shaft (Fig. 2, # 15) carrying a hook (Fig. 2, # 17) at a distal end. The shaft is fitted within a tubular sleeve (interpreted as a catheter) that is slidable over the shaft in a distal direction to cover hook so that the instrument can be inserted through a portal. The hook extends distally from a lateral edge of the shaft and curves inwardly toward a diametrically opposed edge of the shaft. One or both of the proximal and distal edges (Fig. 2, #'s 25 & 27) of the hook can be configured as cutting edges. The hook thus serves as both a grasping and cutting means and is capable of severing a heart chord. The hook would be sized as appropriate for the intended task and clearly would constrain movement of whatever is contained therein. The hook is disclosed as sliding in the sleeve, thus slides in a direction along the sleeve axis.

Claims 1, 58, 59, 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,957,863 to Koblish et al. Koblish et al. teach a biopsy catheter with two movable (rotatable) jaw members on a distal end thereof (Fig. 2), the jaws capable of collecting a biopsy sample. The jaws inherently grasp and cut the sample and are capable of cutting a cardiac valve leaflet. The jaws operate via a wire looped (curved) into the jaws making the wire a part of the grasping member.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,957,863 to Koblish et al. Koblish et al. are discussed above, but do not teach use shape memory materials. A skilled artisan requiring a specific shape for an instrument delivered via catheter to a surgical site would be motivated to shape memory materials, such as Nitinol, to achieve the shape as the use of these materials is well known and obvious.

Claims 64 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,643,248 to Yoon as applied to claim 1 above, and further in view of U.S. Patent 6,626,899 to Houser et al. Yoon is discussed above, but does not teach a stabilizing means. Houser et al. teach a cardiac catheter comprising a collapsible and expandable stabilizer, configured to stabilize the catheter in a body lumen. The stabilizer may comprise, for example, struts or an inflatable balloon (Col. 11, lines 39-43). The use of shaped memory materials for expandable struts is pervasive in the art. It would have been obvious to one skilled in the art to use the expandable stabilizing means as taught by Houser et al. in the invention of Yoon as working in the heart requires such restriction or controlled movement.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,643,248 to Yoon as applied to claim 1 above, and further in view of U.S. Patent Application Publication US 2002/0173811 to Turner et al. et al. Yoon is discussed above, but does not teach catheter within catheter operation. Tu et al. teach an apparatus for use within a heart for valve removal wherein a catheter with cutting and grasping means (Fig. 2, # 77) is delivered to the operational site in a second catheter (Fig. 2, # 19). It would have been obvious to one skilled in the art to use multiple catheters as taught by Tu et al. with the device of Yoon as such use is common to deliver multiple instruments via multiple catheter lumens to a treatment site.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

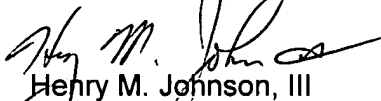
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Henry M. Johnson, III  
Primary Examiner  
Art Unit 3739